

U.S.S.N.: 09/766,362  
 Filed: January 19, 2001  
 AMENDMENT AND RESPONSE TO OFFICE ACTION

### In the claims

1. (Twice amended) A composition for the nasal administration of a drug in a dry powder form having an average particle size of between 10 and 20 microns, in a dosage formulation suitable for administration to the nasal region,

the dry powder form comprising microparticles [formed of] which comprise the drug and a [polymer or diketopiperazine] material selected from the group consisting of diketopiperazines, poly(hydroxy acids), poly(lactic acid), poly(glycolic acid) and copolymers thereof, polyanhydrides, polyesters, polyorthoesters, polyamides, polycarbonates, polyalkylenes including polyethylene and polypropylene, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, poly vinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids including poly(methyl methacrylate), poly(ethyl methacrylate), poly(butylmethacrylate), poly(isobutyl methacrylate), poly(hexylmethacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), polyurethanes and copolymers thereof, celluloses including alkyl cellulose, hydroxyalkyl celluloses, cellulose ethers, cellulose esters, nitro celluloses, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxy-propyl methyl cellulose, hydroxybutyl methyl cellulose, cellulose acetate, cellulose propionate, cellulose acetate butyrate, cellulose acetate phthalate, carboxylethyl cellulose, cellulose triacetate, and cellulose sulphate sodium salt, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), zein, prolamines and hydrophobic proteins, copolymers and mixtures thereof.

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7. (Twice amended) A drug delivery device for nasal administration comprising a drug in a dry powder form having an average particle size of between 10 and 20 microns, in a dosage formulation for administration to the nasal region, and a device for delivering a measured dose of the drug to the nasal mucosa, wherein the dry powder form comprises microparticles [formed of] which comprise the drug and a [polymer or diketopiperazine] material selected from the group consisting of diketopiperazines, poly(hydroxy acids), poly(lactic acid), poly(glycolic acid) and copolymers thereof, polyanhydrides, polyesters, polyorthoesters, polyamides, polycarbonates, polyalkylenes including polyethylene and polypropylene, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, poly vinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids including poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(hexylmethacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), polyurethanes and copolymers thereof, celluloses including alkyl cellulose, hydroxyalkyl celluloses, cellulose ethers, cellulose esters, nitro celluloses, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxy-propyl methyl cellulose, hydroxybutyl methyl cellulose, cellulose acetate, cellulose propionate, cellulose acetate butyrate, cellulose acetate phthalate, carboxylethyl cellulose, cellulose triacetate, and cellulose sulphate sodium salt, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), zein, prolamines and hydrophobic proteins, copolymers and mixtures thereof.

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14. (Twice amended) A method of administering a drug to the nasal region of a patient in need thereof, comprising nasally administering a dry powder form of a drug having an average particle size of between 10 and 20 microns, in a dosage formulation suitable for nasal administration,

wherein the dry powder form comprises microparticles [formed of] which comprise the drug and a [polymer or diketopiperazine] material selected from the group consisting of diketopiperazines, poly(hydroxy acids), poly(lactic acid), poly(glycolic acid) and copolymers thereof, polyanhydrides, polyesters, polvorthoesters, polyamides, polycarbonates, polvalkylenes including polyethylene and polypropylene, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, poly vinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids including poly(methyl methacrylate), poly(ethyl methacrylate), poly(butylmethacrylate), poly(isobutyl methacrylate), poly(hexylmethacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), polyurethanes and copolymers thereof, celluloses including alkyl cellulose, hydroxyalkyl celluloses, cellulose ethers, cellulose esters, nitro celluloses, methyl cellulose, ethyl cellulose, hydroxypropyl cellulose, hydroxy-propyl methyl cellulose, hydroxybutyl methyl cellulose, cellulose acetate, cellulose propionate, cellulose acetate butyrate, cellulose acetate phthalate, carboxylethyl cellulose, cellulose triacetate, and cellulose sulphate sodium salt, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), zein, prolamines and hydrophobic proteins, copolymers and mixtures thereof.